Initial Approval: July 26, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Xalkori® (crizotinib)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Crizotinib (Xalkori®)

CRITERIA FOR APPROVAL (must meet all of the following):

- Patient must have a diagnosis of metastatic non-small cell lung cancer (NSCLC)
- The tumor must be one of the following:
  - Anaplastic lymphoma kinase (ALK)-positive
  - ROS1-positive
- Must be prescribed by or in consultation with an oncologist
- Patient must be 18 years of age or older
- Patient must (one of the following):
  - Females: not be pregnant or breastfeeding and be advised to not become pregnant for at least 45 days after the final dose
  - Males: advised to use effective contraception (e.g. condoms) during treatment and for at least 3 months after the final dose

LENGTH OF APPROVAL: 12 months

Notes:

- Information on FDA-approved tests for the detection of ALK rearrangements in NSCLC is available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm.
- An FDA-approved test for the detection of ROS1 rearrangements in NSCLC is not currently available. Refer to Tests used in the clinical study to identify patients with ROS1 rearrangements in NSCLC: The ROS1 status of NSCLC tissue samples was determined by laboratory-developed break-apart FISH (96%) or RT-PCR (4%) clinical trial assays. For assessment by FISH, ROS1 positivity required that ≥15% of a minimum of 50 evaluated nuclei contained a ROS1 gene rearrangement.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
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DATE	DATE